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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,147	11/24/2003	Itzhak Bentwich	050992.0201.00USCP	1146
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EXAMINER BOWMAN, AMY HUDSON				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/707,147

Applicant(s)

BENTWICH, ITZHAK

Examiner

AMY BOWMAN

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 20 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 20 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/1/08

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 12/1/08 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 6/30/08 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17, 20 and 29-32 are pending in the application.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/1/08 has been entered.

Applicant's amendments and/or arguments filed on 12/1/08 have been considered but are not persuasive for the reasons set forth below.

It is noted that applicant elected without traverse of group I, which is directed to the target gene BIKE, which has the sequence of SEQ ID NO: 2961, in the reply filed on 11/6/2006.

Information Disclosure Statement

The information disclosure statement submitted on 12/1/08 has been considered by the examiner.

Claim Rejections - 35 USC § 101 and 112, First Paragraph

Claims 17, 20 and 29-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial asserted utility, a credible asserted utility, or a well established utility.

The claims are drawn to an isolated nucleic acid selected from the group consisting of a) SEQ ID NO: 354; b) a RNA encoded by (a); and c) the complement of (a) or (b), wherein the complement is identical in length to (a). The claims are drawn to an isolated nucleic acid selected from the group consisting of a) SEQ ID NO: 48; b) a RNA encoded by (a); and c) the complement of (a) or (b), wherein the complement is identical in length to (a). Also claimed are vectors and probes thereof. SEQ ID NO: 354 corresponds to a 22-nucleotide sequence contained within SEQ ID NO: 48.

The specification teaches that Micro RNAs (miRNAs), are short ~22nt non-coding regulatory RNA oligonucleotides, found in a wide range of species, believed to function as specific gene translation repressors, sometimes involved in cell-differentiation (see paragraph [0006]).

The specification discloses that "MIR genes are regulatory genes encoding microRNA's (miRNA), short ~22 nt non-coding RNAs, found in a wide range of species, believed to function as specific gene translation repressors, sometimes involved in cell differentiation" (see paragraph [0006]). The specification discloses, "The present invention relates to a novel groups of regulatory, non-protein coding genes, which are functional in specifically inhibiting translation of target proteins. Each gene in this novel group of genes, here identified as GAM or Genomic Address Messengers, specifically inhibits translation of one or more other 'target' genes by means of complementary hybridization of a segment of the RNA transcript encoded by GAM, to an inhibitor site located in an untranslated region (UTR) of the mRNA of the one or more 'target' genes" (see paragraph [0010]).

The specification discloses that SEQ ID NO: 1 through SEQ ID: 20189 represent genomic sequences of the present invention and that the genomic sequences designated SEQ ID NO: 1 through SEQ ID NO: 200 are nucleotide sequences of 200 gene precursors of respective novel genes of the present invention and genomic sequences designated SEQ ID NO: 201 through SEQ ID NO: 400 are nucleotide sequences of 199 genes of the present invention (see paragraph [0060]).

The specification discloses that GAM is a novel bioinformatically detectable regulatory, non-protein coding, micro RNA (miRNA) gene (see paragraph [0090]). The specification discloses that GAMs represent precursor miRNAs or miRNA-like sequences encoded by a bacterial and/or human genome. Such sequences are

predicted to have a hairpin like structure and to give rise to short, ~22-nt RNAs, which presumably provide gene repression activity.

The specification teaches how to detect and validate the expression of GAMs in cells. The specification discloses that GAM genes encode GAM precursor RNAs, which have structural similarities to miRNA genes. The specification teaches that the GAM precursors look like miRNA genes because they don't encode a protein and they have two-dimensional hairpin like structure, which is typical of RNA encoded by miRNA genes (see paragraph [0093]).

The specification discloses "It is appreciated that specific functions and accordingly utilities of a plurality of GAM genes described by Fig. 8 correlate with, and may be deduced from the identity of the target genes that each of said plurality of GAM genes binds and inhibits, and the function of each of said target genes, as elaborated herein below" (see paragraph [0104]). Figure 8 depicts a general schematic of predicted GAM gene function.

The specification discloses that the present invention discloses 200 novel genes of the GAM group of genes, which have been detected bioinformatically and 1096 novel genes of GR group of genes, which have been detected bioinformatically. The GR genes are disclosed as each encoding a plurality of GAM genes. The specification discloses that Fig. 19 illustrates different utilities of genes of the novel group of genes of the present invention. The specification discloses that a function of GAM genes and GR genes is modulation of expression of target genes related to known diseases, and that

therefore utilities of the novel genes of the present invention include diagnosis and treatment of the diseases (see paragraph [0186]).

The specification discloses "In summary, the current invention discloses a very large number of novel GR genes, each of which encodes a plurality of GAM genes, which in turn may modulate expression of a plurality of target proteins" (see paragraph [0183]).

However, the specification provides no evidence for these assertions. Moreover, the specification discloses a multitude of sequences that have similar structural characteristics such as secondary hairpin folding to MIR precursor hairpins. However, the specification does not provide any evidence for a utility of the instantly recited sequences, SEQ ID NOs: 48 and 354. Applicant is broadly asserting a utility for a multitude of sequences based on miRNA-like structure.

Indeed, the asserted utility of these and thousands of other miRNA-like sequences appears to be based purely on bioinformatic methods for predicting RNA folding and potential gene targets.

Krutzfeldt et al. ((2006) *Nature Genetics* 38:514-519)(of record on the PTO-892 mailed on 10/15/07) state that, in general, the basis for these types of prediction programs is the degree of sequence complementarity between a miRNA and a target UTR, including the presence of a consecutive string of base pairs at the 5' end of the miRNA known as a 'seed' or 'nucleus', and the cross-species conservation of this binding site. On average, 200 genes are predicted to be regulated by a single miRNA.

The authors further state that reviewing the data provided by these algorithms determining candidate targets uncovers the entire gamut of gene categories, such as transcription factors, protein kinases, vesicular trafficking molecules and membrane receptors, suggesting that there is no apparent bias towards one particular function.

Accordingly, while the ability to predict hairpin-like structures and potential gene targets from genomic sequence information appears to be within the state of the art, Krutzfeldt et al. teach that validating the true biological function of any predicted miRNA sequence requires analyzing miRNA expression patterns, as well as testing the effects of miRNA over expression and under expression under different conditions in living cells *in vitro* and *in vivo*.

Thus, while these methods, too, are within the level of skill in the art, Applicant has presented no evidence that any of these validation techniques have, in fact, been carried out with regard to the instantly claimed sequences. There is no evidence verifying the expression of instant SEQ ID NO: 48 comprising SEQ ID NO: 354 in any cell line much less a human cell line or that its expression or absence thereof has been correlated any disease, bacterial or otherwise, or trait.

Further, Applicant has not provided evidence that instant SEQ ID NO: 48 is up or down regulated in any cell or tissue, animal or bacteria, or plays any role in the predisposition of human or mammalian cells to infection.

Applicant's asserted utility appears to be based only on the predicted structure and sequence complementarity of sequences meeting the criteria of "GAM" sequences and on various reports in the prior art describing various genes and their correlation to

diseases. From this, Applicant appears to extrapolate and thereby assert that inhibiting or somehow altering a target gene is beneficial, and that because SEQ ID NO: 48 has a predicted miRNA-like precursor structure and a sequence that is complementarity to some target sequence, it plays a role in inhibiting a target gene and treating a disease.

However, this assertion is not credible. While sequences within SEQ ID NO: 48 may have complementarity to a gene, applicant has not presented any evidence or established any nexus that SEQ ID NO: 48 does target and/or inhibit a specific gene, much less that the expression or inhibition of expression of SEQ ID NO: 48 may be used to prevent or treat a disease associated with a target sequence. The asserted utility is speculative.

The specification does not establish a nexus between any particular disease state, bacterial process, or host cell process, and an altered level or form of the claimed SEQ ID NO: 48 that would enable one of skill to use SEQ ID NO: 48 or SEQ ID NO: 354 to achieve a beneficial effect.

In addition to the bioinformatically predicted utility, described above, the specification generally asserts that Genomic Address Messenger sequences such as instant SEQ ID NO: 48 may be used in various ways. However, none of these asserted uses meet the three-pronged requirement of 35 U.S.C. § 101 regarding utility, namely, that the asserted utility be credible, specific and substantial.

For example, the specification generally asserts that a utility of the novel oligonucleotides of the present invention is detection of GAM oligonucleotides and of GR (Genomic Record) polynucleotides—that diagnosis of expression of

oligonucleotides of the present invention may be useful for research purposes, in order to further understand the connection between the novel oligonucleotides of the present invention and bacterial diseases, for disease diagnosis and prevention purposes, and for monitoring disease progress.

This asserted utility is neither specific nor substantial. Since the same can be done with any polynucleotide, the asserted utility is not specific. Also, because the specification does not disclose any specific function for SEQ ID NO: 48, aside from indicating that it may be expressed in certain cells or present in certain genomes, it is unclear how or why one of skill in the art would use the information obtained by measuring SEQ ID NO: 48 expression for any particular purpose aside from general research. Further, since applicant does not identify whether abnormal SEQ ID NO: 48 expression is causally related to any disease or condition, or whether abnormal SEQ ID NO: 48 (e.g., a polymorphism) predisposes anyone to any disease or condition such as infection, the only recognizable utility of diagnostic probes is as tools for scientific research, and with no indication that anything useful will be discovered. Therefore, the asserted utility is not substantial since the application provides no teaching regarding how to use the probes or expression data for any practical purpose beyond the art-recognized methods of gene expression analysis.

Accordingly, polynucleotide probes derived from the instant invention are simply research intermediates that may help scientists isolate the gene and conduct further experimentation. Such probes can only be used to detect or amplify the genetic material having the same structure as the probes themselves. The probes would provide no

immediate, real-world information about the overall structure or function of the underlying gene, for example, aside from its expression patterns.

Neither the instant specification nor the prior art presents any evidence that instant SEQ ID NO: 48, much less the recited RNA equivalents thereof have any specific biological function. No evidence or information is found either in the specification or the prior art linking SEQ ID NO: 48 with the modulation of any bacterial or mammalian gene or with the conditions that render cells or hosts susceptible to any bacterial infection, for example. No convincing evidence is found teaching any biological function for SEQ ID NO: 48 at all. In fact, no evidence is found suggesting or stating that SEQ ID NO: 48 has been made, isolated, cloned, detected, expressed, or even analyzed in a living cell *in vitro* or *in vivo*.

The specification teaches that GAM7553 gene encodes a GAM7553 precursor RNA that is similar to other miRNA genes because it does not encode a protein. The specification teaches that instant SEQ ID NO: 48 is identical or highly similar to the nucleotide sequence of GAM7553 precursor RNA (see paragraph [50905]).

In summary, no biological or biochemical function has been assigned to SEQ ID NO: 48, apart from the general assertions that it, like the thousands of other sequences described in the sequence listing, may correspond to a miRNA precursor based on folding and have some direct or indirect relation to bacterial disease and/or life cycle.

Thus, Applicant has not demonstrated that SEQ ID NO: 48 may be used in any mode of therapy or as a general means to define and treat bacterial infections.

Thus, the proposed utility of SEQ ID NO: 48 as a therapeutic target or agent, or material resource for preparing diagnostic probes, vectors, a host cells, are simply starting points for further research and investigation into potential practical uses of the claimed polynucleotide.

Brenner v. Manson, 148 U.S.P.Q. 689 (U.S. 1966)

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

Thus, the specification does not teach a specific, substantial, or credible utility for SEQ ID NO: 48, much less any of the RNA equivalents or complements of SEQ ID NO: 48. No target gene has been conclusively identified nor has any evidence been presented linking SEQ ID NO: 48 or fragments thereof with any target gene, bacterial disease or infection, biological function or disorder. A credible, specific, and substantial nexus has not been established.

Claims 17, 20 and 29-32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set

forth above, one skilled in the art clearly would not know how to use the claimed invention.

Without further guidance, one of skill in the art would have to practice a substantial amount of trial and error experimentation, an amount considered undue and not routine, to practice the instantly claimed invention.

Response to Applicant's arguments

Applicant argues that the current application discloses a large number of nucleic acid sequences and provides that each of the disclosed nucleic acids may be used to target and modulate expression of specific gene transcripts. Applicant asserts that the claimed miRNA-related sequences specifically target mRNA transcripts of the target gene LHFPL2 (GAM7553). However, this asserted utility is merely speculated and has not been reduced to practice. The claimed sequences have structural similarity to known miRNA molecules. Applicant is basing the asserted utility upon structural similarities rather than upon any known activity of the instant sequences. miRNA sequences are not fully complementary to the target. Mere structural similarity is not sufficient support to establish utility for the instant sequences, lacking any evidence to the contrary. Furthermore, the claims are directed to SEQ ID NO: 354, SEQ ID NO: 48, the complement of either, as well as any size of RNAs encoded by any of the sequences or complements. Applicant has not established a utility for the breadth of the sequences claimed.

Applicant argues that the instant sequences may be used to bind and regulate mRNA transcripts of LHFPL2 and that LHFPL2 is known to be related to LHFPL, an orthologous gene known to be translocated in chromosomal aberrations in lipomas; And that LHFPL2 is also related to LHFPL3 and LHFPL4. Applicant sets forth that accordingly, modulating LHFPL2 using hsa-miR-196b could have a number of presently available benefits to the public. Applicant has set forth an advantage to modulate LHFPL and hypothesizes that modulation of LHFPL2 would modulate LHFPL simply because they are related in some way. Applicant has not demonstrated that any of the instantly recited sequences would in fact modulate LHFPL2 and that modulation of LHFPL2 would in fact modulate LHFPL, LHFPL3, or LHFPL4, as well as the specific outcome of such.

Applicant argues that there is experimental evidence to demonstrate that hsa-miR-196b is actually expressed in cells and may regulate the asserted target LHFPL2. Applicant points to a declaration of Dr. Ayelet Chajut under 37 CFR 1.132 which presents measuring the effects of an anti-hsa-miR-196b antisense oligonucleotide with a resultant increase of expression of LHFPL3 when targeting hsa-miR-196b.

The showings of the declaration are not commensurate in scope with the instant claims because the instant claims embrace a multitude of possible sequences that would not necessarily act through the hsa-miR-196b pathway and would not necessarily modulate LHFPL3. Furthermore, there is an assumption that SEQ ID NO: 354 actually is the product of the cleavage of the miRNA hairpin. Applicant has not demonstrated that expression of the miRNA hairpin or the single-stranded 22-mer would actually result

in inhibition of LHFPL3. The data does not demonstrate that expression of the hairpin or the single-stranded SEQ ID NO: 354 would actually result in target inhibition, but rather demonstrates that has-miR-196b is present in the cell and can be knocked down with an antagomir.

Cullen (Nature Genetics, Volume 37, Number 11, 2005, pages 1163-1165) teach that the miRNA biogenesis pathway includes three distinct RNA intermediates: the initial pri-miRNA transcript, the pre-miRNA hairpin, and the miRNA duplex and that all can be used as entry points to allow programming of RISC. Cullen teaches that this pathway can be entered with siRNA duplexes, shRNAs, or transcription of artificial pri-miRNA precursors, the third of which giving best results (see page 1164). Cullen teaches that data indicates that siRNAs that are expressed using the natural miRNA biogenesis pathway are more effective than those that are expressed by accessing downstream steps in the pathway, suggesting that miRNA biogenesis may be functionally coupled (i.e. each step may enhance the efficiency of subsequent steps (see page 1165).

Cullen et al. sets forth a schematic of the miRNA biogenesis pathway in Figure 1. There is no evidence that a single-stranded sequence, as instantly claimed, would act in any manner in this pathway because the only step in the pathway that utilizes a single-stranded sequence is in RISC, wherein it appears to be necessary for the miRNA to be in the form of a duplex to be able to load a single-strand into RISC. Therefore, applicant has not demonstrated that SEQ ID NO: 354, SEQ ID NO: 48, the complement of either, or any sized RNA encoded by either sequence, which embraces a multitude of possible sequences, would in fact initiate target inhibition via interacting with RISC, as the state

of the art is such that the pri-miRNA is processed into a miRNA duplex and these processing steps are necessary for the resultant duplex to interact with RISC. Not only would the single-stranded sequences likely not interact with RISC, there is a high probability that the single-stranded sequences would be degraded by nucleases in the cell.

Furthermore, it is unlikely that the instant sequences would act as single-stranded antisense oligonucleotides because these sequences do not have sufficient complementarity with the target that is required by single-stranded antisense oligonucleotides.

The data presented by applicant that targeting hsa-miR-196b is not demonstrative of expression of the instant isolated sequences with resultant target cleavage.

Applicant asserts that the utility is specific because the instantly recited sequences are disclosed as targeting a specific gene transcript. It is acknowledged that the instant specification discloses that the instant sequences are complementary to a specific gene, but has not demonstrated any specific inhibitory effect thereof. The fact that the sequences are complementary to a specific gene sequence does not establish utility. Although the specification correlates the sequences to a gene transcript, the specification does not correlate this to any specific, substantial, and credible utility.

Since the same can be done with any polynucleotide that is complementary to any gene sequence, the asserted utility is not specific. Also, because the specification does not disclose any specific function for SEQ ID NO: 48, aside from indicating that it

may be expressed in certain cells or present in certain genomes, it is unclear how or why one of skill in the art would use the information obtained by measuring SEQ ID NO: 48 expression for any particular purpose aside from general research.

Furthermore, it is important to note that the instant claims are not even closed to SEQ ID NOs: 354 and 48, but are rather directed to a genus of sequences including RNA sequences that are encoded by SEQ ID NOs: 354 and 48, as well as complements of the DNA or RNA sequences, wherein applicant certainly has not established a credible, specific and substantial utility for such complementary sequences or RNA fragments encoded by them.

Furthermore, mismatches are known to alter the activity of the resultant miRNA sequence. Efficacy of a given miRNA is not strictly based upon complementarity of target sequence to the miRNA seed sequence, but rather depends upon other complementarity considerations as well, as evidenced by Mallory et al. (of record and cited on the PTO-892 mailed on 6/30/08). Mallory et al. teach that substitutions between the 5' and 3' regions of a miRNA reduced cleavage rates (see page 3360, for example). Therefore, it cannot be determined whether the instant sequences would act as asserted by applicant without specific testing because applicant is asserting utility simply based upon SEQ ID NOs: 354 and 48 being related to has-mir-196b.

Therefore, the specification does not clearly establish a nexus between the instantly recited sequences (SEQ ID NO: 48; any length of RNA encoded by SEQ ID NO: 48; complement of SEQ ID NO: 48; complement of any length of RNA encoded by SEQ ID NO: 48; SEQ ID NO: 354; any length of RNA encoded by SEQ ID NO: 354;

complement of SEQ ID NO: 354; complement of any length of RNA encoded by SEQ ID NO: 354) and the treatment, diagnosis, or identification of any disease or disorder, as asserted by applicant. Therefore, the asserted utility is not credible and is speculative.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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